

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT
INFRINGEMENT LITIGATION

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) Civ. Action No. 05-356-KAJ (consolidated)
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**DEFENDANTS BARR LABORATORIES, INC.'S AND BARR
PHARMACEUTICALS, INC.'S REDACTED RESPONSE IN OPPOSITION
TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT
REGARDING ANTICIPATION UNDER 35 U.S.C. § 102**

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Date: December 18, 2006

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INTRODUCTION

Plaintiffs, as the summary judgment movants, have the burden to establish that there are no genuine issues of material fact and that they are entitled to judgment as a matter of law on Barr's anticipation defense. Plaintiffs have utterly failed to meet that burden. The undeniable reality here is that there are numerous disputed issues of fact that go to the heart of Barr's anticipation defense, including whether the prior art article, "Medical Management of Dementia," by P.A. Bhasker discloses Alzheimer's disease and a treatment for Alzheimer's disease using galanthamine. Plaintiffs have ignored these genuine factual disputes, preferring instead to rely on unsupported attorney rhetoric and argument. That, however, is not enough to support a motion for summary judgment. This case is not amenable to summary judgment precisely because there are so many genuine issues of material fact on the question of anticipation. Plaintiffs have not shown otherwise. Moreover, even if the Court were to find that there are no genuine issues of material fact, Plaintiffs motion should be denied because they are not entitled to judgment as a matter of law. As discussed herein, Bhasker does disclose each of the limitations of claim 1. Accordingly, Plaintiffs' motion should be denied.

STATEMENT OF FACTS

Alzheimer's disease was first described by Alois Alzheimer in 1907. For many decades thereafter, Alzheimer's disease was thought to be a rare disease in middle-aged persons, which disease did not include senile memory loss and dementia that occurred in elderly persons. Gradually, however, science came to recognize that Alzheimer's disease encompassed both a presenile and senile form, and was, unfortunately, anything but rare in the elderly.

In the mid-1970s, it became known that the neurotransmitter acetylcholine, which is regulated by the cholinergic system, is important in memory.¹ (See Sworn Affidavit of Dr. Allan I. Levey, attached to the Farnan Declaration as Exhibit 1, at ¶ 7; see Opening Expert Report of Dr. Allan Levey at ¶ 30, attached to the Farnan Declaration as Exhibit 3).² At about the same time, the progressive fallout of cholinergic neurons in Alzheimer's disease brains was discovered. (*Id.* ¶ 33). This major discovery was important because acetylcholine is created by the brain's cholinergic neurons. The level of acetylcholine in the brain decreases as the number of functioning cholinergic neurons decrease. Most importantly, this acetylcholine deficiency was found to correlate with the severity of dementia. (*Id.* at ¶ 29).

It was hypothesized that by increasing the level (or decreasing the decline) of acetylcholine in the brain, one could provide a beneficial effect on the symptoms of those suffering from Alzheimer's disease. (*Id.*). This became known as the "cholinergic deficit hypothesis," which posited that there is a loss of acetylcholine in the brains of Alzheimer's disease patients, and that this deficiency contributes to the symptoms of the disease. (*Id.*). One such set of symptoms of Alzheimer's disease that have long been recognized is the diminution of higher cortical functions - including language, executive function, learning, memory, visual perception, judgment, abstraction, and skilled movements. (*Id.* at ¶ 99).

Cholinesterase breaks down acetylcholine in the brain and thus a cholinesterase inhibitor decreases (or "inhibits") the decline of acetylcholine in the brain. One of the

¹ Acetylcholine is a neurotransmitter that acts as a chemical messenger in the nervous system, essentially sending a message from one nerve to another. (Ex. 3 at ¶ 30).

² All references to "Exhibit _" or "Ex. _" refer to the exhibits attached to the Declaration of Brian E. Farnan filed contemporaneously herewith.

most well-known (and ultimately, the only successful) pharmacological approaches to the treatment of Alzheimer's disease that grew out of the cholinergic deficit hypothesis was the use of a class of drugs known as reversible cholinesterase inhibitors, of which galanthamine is a member. (*Id.* at ¶ 35). This is because these compounds were an established class of drugs that had been shown to increase acetylcholine in the brain. (*Id.*) There were several highly visible, published studies conducted in the late 1970s and early 1980s with other reversible cholinesterase inhibitors that showed improvement in memory in Alzheimer's disease patients. (*Id.* at ¶¶ 32, 36, 74-76, 78).

After these studies were published, Dr. Bonnie Davis filed her patent application in 1986, which application eventually led to U.S. Patent 4,663,318 (the "'318 patent," attached to the Farnan Declaration as Exhibit 5). Claim 1 of the '318 patent is directed to a "method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof."

Prior to Dr. Davis filing her patent application, Dr. Bhasker published his article "Medical Management of Dementia" (hereinafter "Bhasker," attached to the Farnan Declaration as Exhibit 6). Bhasker teaches the management (or "treatment") of "irreversible" or "progressive dementia," which he defines as a category of dementias characterized by "a progressive fall-out of neurons and [where] the course of the illness is rapidly downhill." (Ex. 6 at 45). As stated above, it was well known in 1986 that Alzheimer's disease was characterized by a "progressive fall-out of neurons,"

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Ex. 3 at ¶ 99;

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Additionally, at the time Dr. Davis filed her patent application in 1986, the most prevalent form of irreversible or progressive dementia was, by far, Alzheimer's disease. (See Ex. 3 at ¶ 99).

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Moreover, it was well-known in 1986 that the course of Alzheimer's disease and related dementias could be characterized as "rapidly downhill." (Ex. 3 at ¶ 99; Levey Rebuttal Report at ¶ 10, attached to the Farnan Declaration as Exhibit 4). In short, Bhasker discloses Alzheimer's disease. (*Id.* at ¶ 99).

Bhasker goes on to describe managing (or "treating") the "irreversible" or "progressive" dementias in terms of "the restoration of higher cortical functions" through "deinhibition," which Bhasker defines as "the facilitation of acetylcholine activity by giving small daily doses of Cholinesterase inhibitors (Neostigmine, Gallanthamine, etc.)." (Ex. 6 at 46). In the context of the management or treatment of progressive dementias, Bhasker states that "[t]he restoration of cortical function is difficult and was once considered impossible; but it has lately gained importance," and that galanthamine has been used to improve higher cortical function by facilitating acetylcholine activity. (*Id.*). By 1986, the diminution of higher cortical functions was recognized as one of the central symptoms of Alzheimer's disease. (Ex. 3 at ¶ 99). At that time, it was known that the facilitation of acetylcholine activity through the administration of different cholinesterase inhibitors was already being done by researchers in the field. (*Id.* at ¶¶ 32-36).

Bhasker's reference to "treatment" refers to instances where "the dementia can be cleared up and the patient can have a complete cure." (Ex. 6 at 45). Conversely, Bhasker's use of the phrase "medical management of dementia" is broad, encompassing the management of the symptoms of dementia through the use of traditional care-giving, the use of drugs, and even surgery. (*Id.* at 45-47). It appears clear, then, that when read in context, Bhasker's use of the word "treatment", contrary to the meaning of the term in the '318 patent, means "cure." The term management, on the other hand, means the same as the word treatment in the '318 patent, *i.e.*, acting on the symptoms of the disease.). In sum, Bhasker discloses methods of treating Alzheimer's disease by administering galanthamine to a patient.

It is significant to note that more than 30 years after Bhasker's publication, unfortunately there is still no cure for Alzheimer's disease. However, there are "treatments" which improve higher cortical functions, of which the administration of galanthamine is one.

With this understanding of Bhasker, Defendants, therefore, asserted as an invalidity defense to be tried that Bhasker anticipates the claimed invention of the '318 patent.³ Plaintiffs have moved for *partial* summary judgment regarding anticipation, claiming that Bhasker "does not disclose any of the elements" of Claim 1 of the '318 Patent." (Br. at 2). For the reasons discussed above and below, Plaintiffs are incorrect and thus their motion should be denied.

³ Barr did not move for summary judgment on anticipation, notwithstanding Barr's position that Bhasker plainly anticipates each and every limitation of claim 1, because Barr did not want to consume the Court's time with a motion where it is indisputable that there are genuine issues of material fact.

ARGUMENT

I. Proper Standard for Summary Judgment

Summary judgment is appropriate only “if there are no genuine issues of material fact and the movant is entitled to judgment as a matter of law.” *Nystrom v. TREX Co., Inc.*, 424 F.3d 1136, 1141 (Fed. Cir. 2005). In considering the motion, the court must view the evidence in the light most favorable to the non-movant and must draw all reasonable inferences in favor of the non-movant. *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) (“The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor”). “The moving party bears the burden of demonstrating the absence of material fact.” *Applied Medical Resources, Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1331-32 (Fed. Cir. 2006). “Although patent issues are as amenable to summary resolution as other matters, when material facts are disputed, and testimonial, documentary, and expert evidence are needed for their resolution, summary adjudication is not indicated.” *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 872 (Fed. Cir. 1991).

Patent invalidity on the basis of anticipation is a question of fact. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). It requires a showing that each limitation of a claim is found in a single reference, either expressly or inherently. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1369 (Fed. Cir. 2005). “[T]he question of whether a claim limitation is inherent in a prior art reference is a factual question on which evidence may be introduced.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (citing *Continental Can Co. USA v. Monsanto Co.*,

948 F.2d 1264, 1268 (Fed. Cir. 1991)). In order to establish anticipation, “[t]here must be no difference between the claimed invention and the reference disclosure, *as viewed by a person of ordinary skill in the field of the invention.*” *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991) (emphasis added). In deciding whether a patent is invalid due to anticipation, expert testimony is not only useful, it is often necessary: “Typically, testimony concerning anticipation *must be testimony from one skilled in the art* and must identify each claim element, state the witnesses’ interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference.” *Schumer v. Lab Computer Sys., Inc.*, 308 F.3d 1304, 1315-16 (Fed. Cir. 2002) (emphasis added).

In their presentation of the case law, Plaintiffs artfully have blurred the line between a defendant *attempting to prove* anticipation at trial and a plaintiff *attempting to dismiss* an anticipation defense through a summary judgment motion. Plaintiffs have moved for summary judgment, not Barr. Therefore, it is Plaintiffs burden to show the absence of a genuine issue of material fact and that they are entitled to judgment as a matter of law. They have failed to do so.⁴

II. At A Minimum, There Are Genuine Issues of Material Fact As To Whether Bhasker Anticipates Claim 1

Plaintiffs simply cannot dispute that there are genuine disagreements between Plaintiffs’ and Defendants’ experts over whether Bhasker discloses each of the limitations of claim 1.

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⁴ If the Court finds that there are no genuine issues of material fact, it is Barr’s position that Plaintiffs motion must still be denied because they have not proven that they are entitled to judgment as a matter of law. On the contrary, they have not advanced any evidence in support of their position. Barr, however, has set forth clear and convincing evidence that Bhasker does disclose each and every limitation of claim 1 and therefore the claim is invalid as anticipated.

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In situations such

as this, where there is a so-called “battle of the experts”, summary judgment is inappropriate. *See, e.g., Quad Envtl. Techs. Corp.*, 946 F.2d at 872 (“when material facts are disputed, and testimonial, documentary, and expert evidence are needed for their resolution, summary adjudication is not indicated.”) Plaintiffs have ignored this factual dispute. When the factual dispute is considered, however, there simply is no question that summary judgment is not warranted.⁶

A. Whether Bhasker Describes Alzheimer’s Disease and Related Dementias Is A Genuine Issue of Material Fact

Plaintiffs’ assertion that “Bhasker *indisputably* does not itself *describe* Alzheimer’s disease” does not pass the straight-face test. (Br. at 7-8 (emphasis added)). Whether Bhasker describes Alzheimer’s Disease and related dementias is one of the central disputed facts between the parties. Defendants’ experts have opined that Bhasker does disclose Alzheimer’s disease;

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Defendants’ expert evidence establishes that one skilled in the art in 1986 would have read Bhasker to describe Alzheimer’s disease because it discloses dementia characterized by “progressive fall-out of neurons where the course of the illness is rapidly

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⁶ Because it is critical to view a piece of prior art through the eyes of one of ordinary skill in the art when analyzing an anticipation defense, it is important to understand what that level of skill is. Defendants’ experts have defined a person of ordinary skill in the art with respect to the ‘318 patent as of January 15, 1986 as “an M.D. or Ph.D. interested in the field of Alzheimer’s disease research (which would include M.D. and Ph.D. students as well as doctors and researchers in the fields of pharmacology, geriatrics, psychiatry, neurology, neuroscience or pharmacy), who, as a result of such training and/or interest, would have knowledge of the cholinergic deficiency hypothesis of Alzheimer’s disease, the role of acetylcholine in memory, and pharmacological strategies and approaches for treating Alzheimer’s disease and related dementias.” (Ex. 3 at ¶ 19).

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downhill.”

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In his Opening Expert Report, Dr. Levey opined that:

I am of the view that [Bhasker] is describing irreversible dementias generally, which *necessarily* includes the most prevalent of the irreversible dementias, Alzheimer’s disease.

(Ex. 3 at ¶ 99). Dr. Levey further opined that “Dr. Bhasker’s characterization of the irreversible dementias which he is referring to as having ‘a progressive fall-out of neurons and the course of the illness is rapidly downhill’ [citing Bhasker at 45]”, refers to Alzheimer’s disease and related dementias. (Ex. 3 at ¶ 99; *see also* Ex. 4 at ¶ 10). Furthermore, Defendants’ expert has opined that Bhasker discloses Alzheimer’s disease because the article discusses the treatment of progressive dementia in terms of “restoration of higher cortical functions.” (Ex. 6 at 46). Dr. Levey opined in his expert report that:

Higher cortical functions include language, executive function, learning, memory, visual perception, judgment, abstraction, and skilled movements (praxis). Diminution of these higher cortical functions *have been long as recognized* symptoms of Alzheimer’s disease dementia.

(Ex. 3 at ¶ 99 (emphasis added)).⁷ Therefore, it is Defendants’ expert’s opinion that one of ordinary skill in the art reading Bhasker in 1986 would have read the article to disclose Alzheimer’s disease.⁸

⁷ At his deposition, Dr. Levey further testified that “[o]ne skilled in the art would know that most individuals who have a steady decline and loss of cortical functions, that pathologically it’s due to most commonly Alzheimer’s disease.” (Deposition of Dr. Allan J. Levey, at 248:19-22, attached to the Farnan Declaration as Exhibit 11)

Despite Plaintiffs' attempts to make it appear otherwise, the fact that the Bhasker article does not use the term "Alzheimer's disease" is not case determinative. It is black letter law that an anticipating reference "need not recite the elements of the patent claim in language identical to the language used in the claim, so long as the reference teaches the entirety of the invention." *Forest Laboratories, Inc. v. Ivax Pharm., Inc.*, 438 F.Supp.2d 479, 485 (D. Del. 2006). Moreover, where a reference does not expressly disclose a claim element(s), the reference may still be anticipating where a person of ordinary skill in the art would understand the reference as disclosing that element(s), and such element(s) was within the knowledge of that person. *Heliflex Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1139, 1347 (Fed. Cir. 2000); *see also In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995) (noting that a reference anticipates "even if it does not specifically disclose" the claim limitation if the limitation "is within the knowledge of a skilled artisan."); *Discovision Associates v. Disc Manufacturing, Inc.*, 25 F.Supp.2d 301, 344 (D. Del. 1998) (noting that "anticipation may be established if a missing claim element is within the knowledge of one of ordinary skill in the art."). "Recognition of the inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation." *LP Matthews, LLC v. Bath & Body Works, Inc. et al.*, 2006 US Dist. LEXIS 76114 at 12 (D. Del. 2006).

Moreover, Plaintiffs continuously confuse the proper standard necessary to overcome a motion for summary judgment. For example, in criticizing Barr's reading of

Bhasker, Plaintiffs state “[a]s a matter of law, Defendants cannot meet their burden to prove anticipation by clear and convincing evidence with such a twisted and contrary reading of Bhasker.” (Br. at 6). First, whether Defendants’ experts’ reading of Bhasker is “twisted” and “contrary” smacks of a credibility determination of Defendants’ experts, clearly a question of fact to be resolved at trial. Second, for purposes of this motion, the threshold issue is not what Defendants can or cannot prove, but rather, whether Plaintiffs have met their burden of proving that there are no genuine issues of material fact that could establish anticipation. Based on the testimony and reports of Defendants’ experts, Plaintiffs have not, and cannot meet this burden.

Thus, *at the very least*, there is a genuine issue of material fact regarding whether Bhasker discloses Alzheimer’s disease that renders Plaintiffs’ motion for partial summary judgment inappropriate. Bearing in mind that the evidence is to be viewed in a light most favorable to Defendants and all reasonable inferences drawn in their favor, denial of Plaintiffs’ motion is all the more warranted.

B. Whether Bhasker Describes Progressive Dementias As Treatable Is A Genuine Issue of Material Fact

Plaintiffs’ assertion that Bhasker describes “progressive dementias” as “untreatable,” and therefore that “Bhasker’s express teachings *contradict* defendants’ anticipation claim” is disingenuous. (Br. at 7 (emphasis in original)). As an initial matter, the exact language of Bhasker is “[w]ith regard to progressive dementia, there appears very little to offer. *Only management and no treatment is possible*,” (Ex. 6 at 45 (emphasis added)). The article does not state that progressive dementia is “untreatable” as Plaintiffs maintain. (Br. at 6). It seems clear from a full reading of Bhasker that Bhasker uses the term “treatment” to mean “cure” and “management” to mean

“treatment,” the way the term is used in the ‘318 patent. Defendants’ expert, Dr. Levey, makes this very point:

It also is my opinion that Plaintiffs’ experts all misconstrue the true meaning of Bhasker’s article by failing to make the distinction between symptomatic treatment and curative treatment of progressive dementia. In my opinion, Bhasker’s reference to treatment refers to instances where the “dementia can be cleared up and the patient can have a complete cure.” (Bhasker at 45). Conversely, it is my opinion that Bhasker’s use of the phrase “medical management of dementia” encompasses the management of symptoms of dementia, including the behavioral and cognitive symptoms, through the use of drugs. (Bhasker 45-47). While Bhasker did state that *galanthamine* would not *cure* progressive dementia, the article suggests that *galanthamine* has the ability to provide symptomatic improvement.

(Ex. 4 at ¶ 14 (emphasis added)). “Symptomatic improvement” is all that the invention of the ‘318 patent claims, as, unfortunately, even today there still is not a known curative treatment for Alzheimer’s disease.

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Further, Bhasker discusses the use of psychiatric care, general surgical therapy, and the use of drugs (including galanthamine) under the umbrella of “management of dementia.” (Ex. 6 at 46). Therefore, as Dr. Levey stated, the term “treatment” used by Bhasker (and quoted by Plaintiffs) refers to a “cure,” and therefore, in no way “contradicts” Barr’s anticipation claim, as Alzheimer’s disease is still today “untreatable” in the sense that there is no known cure.⁹ At the *very least*, the interpretation of what

⁹ This point is further evidenced given the language of the opening paragraph of Bhasker, which states: “The corrective treatment is usually therefore, one associated with a gloomy outlook . . . [t]his gloomy picture is thoroughly wiped out and a favorable result readily obtained when one of the treatable underlying causes is detected; the prognosis becomes ‘excellent’ when the correctable cause is diagnosed early and found to be a metabolic or endocrine deficit. In such cases, the dementia can be cleared up and the patient can have a complete ‘cure’.” (Ex. 6 at 45). This language clearly suggests that Bhasker is equating “treatment” with “cure.”

Bhasker is referring to by the use of the word “treatment” is a genuine issue of material fact, which is not appropriate for resolution on summary judgment.¹⁰

C. Whether Bhasker Describes Galanthamine As A Treatment For Alzheimer’s Disease Is A Genuine Issue of Material Fact

Plaintiffs further assert that it is “beyond the pale of reasonable dispute to contend...that a description of galantamine in connection with ‘local brain damage’ instead describes its use for that wholly different disease [Alzheimer’s].” (Br. at 6). While Bhasker’s discussion of the use of galanthamine occurs at least partially in the context of local brain damage, the overall context of the discussion must be understood, not ignored as Plaintiffs have done in their motion. Dr. Levey testified that “I think you have to interpret that in context So there’s a general principle he’s talking about, deinhibition, and they give examples of how -- of how that can help.” (Ex. 11 at 256:12-15).

Dr. Levey further testified that Bhasker characterized progressive dementias as affecting “complex structural or functional changes in the most sophisticated mechanisms of the brain. So one skilled in the art would know that the most sophisticated mechanisms of the brain are the higher cortical functions.” (Ex. 11 at 249:18-21). “[H]igher cortical functions include language, executive function, learning, memory, visual perception, judgment, abstraction, and skilled movements. Diminution -- diminution of these higher cortical functions have been . . . long . . . recognized symptom of Alzheimer’s disease dementia.” (Ex. 11 at 247:11-16).

¹⁰ To the extent that Plaintiffs are suggesting that Bhasker somehow “teaches away” from the use of galanthamine as a treatment for Alzheimer’s disease, their argument is not supported by the case law. See *Celeritas Techs. v. Rockwell Int’l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998) (“A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. Thus, the question whether a reference ‘teaches away’ from the invention is inapplicable to an anticipation analysis.” (citation omitted)).

Dr. Levey also testified that “[o]ne skilled in the art would know that most individuals who have a steady decline in loss of cortical functions, that pathologically it’s due to most commonly Alzheimer’s disease.” (Ex. 11 at 248:19-22). “[I]t would be certainly part of the basic teaching in medical school and other clinical training and widely available for anybody who is trying to learn about the disease.” (Ex. 11 at 249:6-9). “[I]t almost seems implicit to me or inherent in the paper that he’s linking abnormalities and cholinergic system to higher cortical function. I think that’s inherent in the paper.” (Ex. 11 at 254:17-20). “[O]ne skilled in the art would have been aware that there is a general effect of acetylcholine on many of these higher brain functions.” (Ex. 11 at 256:22-257:1-4).

Therefore, one of ordinary skill in the art in 1986 would understand Bhasker as suggesting deinhibition -- defined in Bhasker as “the facilitation of acetylcholine activity by giving small daily doses of Cholinesterase inhibitors (Neostigmine, *Gallanthamine*, etc.)” -- as a way to treat irreversible or progressive dementia.¹¹ Again, *at the very least*, drawing all reasonable inferences in Defendants’ favor, this is a factual issue that is not appropriate for summary judgment.

¹¹ Dr. Domino’s testimony supports this conclusion:

Q: Let me ask you to be clear would a person of ordinary skill in the art reading the Bhasker article in January 1986 read the article to describe galanthamine as a treatment for Alzheimer’s disease?

(Objection omitted)

A: If it included not only the whole -- the whole article and all of the theory behind the article, the answer is yes.

(Deposition of Dr. Edward Domino at 175-176, attached hereto as Exhibit 12).

III. Plaintiffs' Statement Of The Law Of Anticipation Is Incomplete And Misleading

Not only have Plaintiffs failed to show the absence of a genuine issue of material fact and that they are entitled to judgment as a matter of law regarding Defendants' anticipation defense, their discussion of the law of anticipation is flawed. Plaintiffs rely on *Forest Labs* for the proposition that, in an anticipation analysis, "one skilled in the art cannot supply missing elements through his or her knowledge." (Br. at 7 (quoting *Forest Labs.*, 438 F.Supp.2d at 485)). Plaintiffs use this language to support their claim that Bhasker does not contain all of the limitations of Claim 1 of the '318 patent, and that Dr. Domino's testimony somehow "confirmed" that Bhasker does not contain all of the limitations of Claim 1 of the '318 patent. (Br. at 7). Plaintiffs' contentions are incorrect for several reasons.

First, Plaintiffs' statement of the law is incomplete. As an initial matter, Plaintiffs' selective quotation from the *Forest Labs* decision must be put into context. Plaintiffs fail to note that the sentence immediately following their selected quotation goes on to say that "[s]tated another way, '[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.'" *Forest Labs.*, 438 F.Supp.2d at 485 (citation omitted) (emphasis added). Furthermore, earlier in the same paragraph of the opinion, the Court noted that an anticipating reference "need not recite the elements of the patent claims in language identical to the language used in the claim, so long as the reference *teaches the entirety of the invention.*" *Id.* (emphasis added). Whether a reference "teaches the entirety of the invention" is, of course, to be viewed through the lens of one of ordinary skill in the art.

Within this context, it is clear that *Forest Labs* is consistent with the general principle of law that where a reference does not expressly disclose a claim element(s), the reference may still be anticipating where a person of ordinary skill in the art would understand the reference as disclosing that element(s), and such element(s) was within the knowledge of that person of ordinary skill in the art. *Heliflex* 208 F.3d at 1347; *see also In re Graves*, 69 F.3d at 1152 (noting that a reference anticipates “even if it does not specifically disclose” the claim limitation if the limitation “is within the knowledge of a skilled artisan.”); *Discovision Associates*, 25 F.Supp.2d at 344 (noting that “anticipation may be established if a missing claim element is within the knowledge of one of ordinary skill in the art.”); *Motorola, Inc. v. Interdigital Technology Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) (noting that the disclosure requirement “presupposes the knowledge of one skilled in the art of the claimed invention.”).¹² As discussed above, Defendants’ experts have opined that Bhasker discloses each of the limitations of claim 1.

Second, as discussed above, contrary to Plaintiffs’ assertion that Dr. Domino’s testimony “confirmed” that Bhasker does not contain all of the limitations of the asserted claims of the ‘318 patent, Plaintiffs’ own characterization of Dr. Domino’s testimony actually supports *Defendants’* position in this case. A person of ordinary skill in the art (*See supra* footnote 6), reading the Bhasker reference in 1986, *would* (in Plaintiffs’ language) “have knowledge about the characteristics of Alzheimer’s disease, and specifically knowledge about the cholinergic deficit associated with that disease” and would “know that galantamine crosses that blood-brain barrier.” (Br. at 7). Such

¹² As this Court may or may not know, the other case relied upon heavily by Plaintiffs in their Brief, *Impax Labs. v. Aventis Pharms., Inc.*, 235 F.Supp.2d 390 (D. Del. 2001), was recently vacated by the United States Court of Appeals for the Federal Circuit. *See Impax Labs. v. Aventis Pharm., Inc.*, No. 05-1313, 2006 WL 3346151 (Fed. Cir. Nov. 20, 2006), attached to the Farnan Declaration as Exhibit 13. Any reliance by Plaintiffs, therefore, on this decision is inappropriate.

knowledge would “explain, but not expand” the meaning of the Bhasker reference to one of ordinary skill in the art in 1986. *See In re Baxter Travenol Labs*, 952 F.2d 388, 391 (Fed. Cir. 1991)(citing *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576-77 (Fed. Cir. 1991). Contrary to Plaintiffs’ assertions, this is entirely permissible, and is, in fact, the reason for the requirement that anticipation be analyzed through the lens of one of ordinary skill in the art.

IV. Partial Summary Judgment In Plaintiffs’ Favor Will Not Speed Up the Resolution of This Case; It Will However Severely Prejudice Barr By Eliminating A Defense Where There Are Genuine Issues of Material Fact

In addition to relying on Bhasker for their anticipation defense, Defendants have asserted Bhasker as part of their obviousness defense. (See Defendants Barr Pharmaceuticals, Inc.’s and Barr Laboratories, Inc.’s Supplemental Objections and Response to Plaintiffs’ Interrogatory No. 2 at 4-10, attached to the Farnan Declaration as Exhibit 14). The exact same expert witnesses for Defendants who will testify on the issue of obviousness using Bhasker (amongst other prior art) will testify on the issue of Bhasker anticipating the invention of the ‘318 patent. Accordingly, not only is Plaintiffs’ motion defective on the merits, its resolution in Plaintiffs’ favor will not speed up the resolution of this case, which is the fundamental purpose of a motion for partial summary judgment. *Byrne v. Dew, et al.*, 1992 U.S. Dist. LEXIS 5703 at 17 (N.D. Ill. 1992) (Because testimony regarding the issue related to the partial summary judgment motion and the remaining issue of the case “will come from the same witnesses, partial summary judgment on this issue will not speed up the litigation to any great extent,” and thus, the partial summary judgment motion was denied). Thus, in addition to its lack of merit, the

motion should be denied for this reason as well. *Byrne*, 1992 U.S. Dist. LEXIS 5703 at 17.¹³

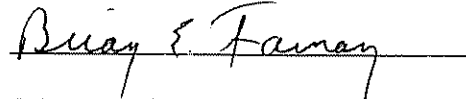
CONCLUSION

For all of the foregoing reasons, Barr respectfully requests that Plaintiffs' Motion For Partial Summary Judgment be denied.

¹³ Moreover, Plaintiffs' motion for summary judgment is premature as the parties are presently awaiting the Court's claim construction. "Before the factual question of anticipation may be addressed, a court must first properly construe the claims before it." *Akamai Techs, Inc. v. Cable & Wireless Internet Servs., Inc.*, 344 F.3d 1186, 1195 (Fed Cir. 2003). Since Plaintiffs' motion for summary judgment lacked the Court's claim construction, the precise scope of the invention is unclear. *See The Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1319 (Fed Cir 2004). It is evident that the analysis of anticipation begins with construing the limitations of the claims in the patent at issue. *Id.* The claim construction, in turn, "guide[s] the analysis of the allegedly anticipating prior-art reference." *Id.* Therefore, at this point, it is impossible to know exactly what Bhasker must disclose if it is to anticipate the '318 patent.

Dated: December 18, 2006

Respectfully submitted,

A handwritten signature in cursive script, reading "Brian E. Farnan", is written over a horizontal line.

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